

Amendments to the Specification:

Please replace paragraph [0007] with the following amended paragraph:

[0007] FIG. 1 through 8 provide various schematic illustrations of exemplary controlled release soft-cap dosage forms according to the present invention.

FIG. 9A through 9D provide a series of schematic representations illustrating a method for forming a plug to seal exposed portions of osmotic composition at an exit orifice included in a dosage form according to the present invention.

FIG. 10 and FIG. 11 provide schematic representations of an exemplary soft-cap controlled release dosage form according to an embodiment of the invention.

FIG. 12 through FIG. 14 provide schematic representations illustrating a method of forming a seal on the inner surface of an exit orifice included in a dosage form according to the present invention.

FIG. 15. provides a schematic illustration of an exemplary hard-cap controlled release dosage form according to the present invention.

FIG. 16 provides a graph illustrating the results of a study conducted to evaluate the solubility of raw megestrol acetate and nanoparticulate megestrol acetate in AIF the presence of various concentrations of a self-emulsifying carrier useful in the self-emulsifying nanosuspension of the present invention.

FIG. 17 provides a graph illustrating the results of a study conducted to evaluate the stability of megestrol acetate solubilized in an emulsion formed by a self-emulsifying carrier useful in the self-emulsifying nanosuspension of the present invention.

FIG. 18 provides a graph illustrating the release profile of megestrol acetate provided by a dosage form according to the present invention.

FIG. 19 provides a graph illustrating the release profile of megestrol acetate provided by a second dosage form according to the present invention.

FIG. 20. provides a graph ~~and table setting~~ for the results of a PK study conducted to evaluate the bioavailability of megestrol acetate provided by various different dosage forms, including two different dosage forms according to the present invention.

~~Table 1~~ FIG. 21 provides physical properties of saturated fatty acids ranging from saturated C6 fatty acids to saturated C18 fatty acids.

~~Table 2~~ FIG. 22 describes the formulations delivered by the different dosage used in the PK study described in Example 5.

~~Table 3~~ FIG. 23 details the Liquid Chromotography/Mass Spectroscopy conditions used to evaluate the plasma concentration of megestrol acetate as part of the PK study described in Example 5.

Please replace paragraph [0010] with the following amended paragraph:

[0010] In order to achieve a self-emulsifying nanosuspension that is flowable at physiologic temperatures, however, the saturated fatty included as the oil phase of the self-emulsifying nanosuspension of the present invention must be chosen carefully. It has been found that saturated fatty acids that are smaller than C8 fatty acids do not exhibit sufficient hydrophobicity to consistently create a multiphase emulsion *in-situ* upon exposure to aqueous media. Therefore, the self-emulsifying nanosuspension of the present invention is formulated using a saturated fatty acid that is a C8 fatty acid or larger. However, the melting point of saturated fatty acids increases undesirably as the size of the saturated fatty acid increases beyond C12 fatty acids. Even after mixture with one or more excipients, the melting points of saturated fatty acids larger than C12 are too high to provide a flowable drug formulation at physiologic temperatures. Therefore, the oil phase of the self-emulsifying nanosuspension of the present invention is preferably formed using saturated C8 to C12 fatty acids. ~~Table 1~~ FIG. 21 provides physical properties of saturated fatty acids ranging from saturated C6 fatty acids to saturated C18 fatty acids.

Please replace paragraph [0011] with the following amended paragraph:

[0011] Though the oil phase of the self-emulsifying nanosuspension of the present invention may include a single type of saturated fatty acid or a mixture of different saturated fatty acids, in each embodiment, the oil phase of the self-emulsifying nanosuspension of the present invention

will include an amount of C8, C10, or C12 fatty acid. In a particularly preferred embodiment, capric acid, a saturated C10 fatty acid, serves as the oil phase of the self-emulsifying formulation of the present invention. As can be appreciated by reference to ~~Table 1~~ FIG. 21, capric acid has a melting temperature of 31° C and a low solubility in water. The self-emulsifying nanosuspension of the present invention includes between about 10 wt% and about 80 wt% saturated fatty acid, with the saturated fatty acid preferably accounting for about 35 wt% to about 45 wt% of the self-emulsifying nanosuspension.

Please replace paragraph [0075] with the following amended paragraph:

[0075] A five-arm PK study was conducted to evaluate the bioavailability of megestrol acetate provided by several different dosage forms. The study included administering various dosage forms to three fasted mongrel dogs. The dosage forms administered in the study included controlled release dosage forms manufactured according to EXAMPLE 1 (“4% nanosuspension hard-cap”) and EXAMPLE 2 (“16% nanosuspension hard-cap”), commercially available 20 mg Megace® tablets, hard-cap controlled release dosage forms containing a self-emulsifying solution of megestrol acetate (“controlled release SES dosage forms”), and immediate release hard-caps containing a self-emulsifying solution of megestrol acetate (“IR SES dosage forms”). The formulations delivered by the different dosage forms are described in ~~Table 2~~ FIG. 22.

Please replace paragraph [0078] with the following amended paragraph:

[0078] The dosage forms were dosed to the dogs in a fasted state using oral gavage. The same group of three dogs was used throughout the study, with each of the three dogs being dosed with each of the different dosage forms. In each arm of the study, the dogs were given a 20 mg dose of megestrol acetate. In order to achieve a 20 mg dose, each dog was administered two controlled release SES dosage forms and two IR SES dosage forms, as each of these dosage forms provided only a 10 mg dose of megestrol acetate. Plasma samples were taken from each dog at 0, 0.5, 1, 2, 4, 6, 8, and 10 hours after dosing each of the dosage forms, with additional plasma samples being taken from each dog at 12 hours and 24 hours after administration of the

three controlled release dosage forms. The plasma concentration of megestrol acetate in each sample was evaluated using an LC/MS method with a minimum detection limit of 1 ng/ml. The LC/MS conditions are provided in ~~Table 3~~ FIG. 23.